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EXAMINER
MOONAN, FRANCIS P

ART UNIT	PAPER NUMBER
1638	17

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/698,903	WESTON ET AL.	
	Examiner	Art Unit	
	Francis P Moonan	1638	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above claim(s) *23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12, 14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Originally presented Claims 1-22 were first subject to a Restriction Requirement in Paper No. 11 filed on 14 December 2001; wherein election of restricted groups of transgenic plant products (Groups I an II) and kit products (Group III) were required.

In Paper No. 13 filed on 22 January 2002, Applicant cancelled Claims 1-22, and requested that claims 23-34 be newly added. Claims 1-22 were cancelled, and Claims 23-34 were newly added.

In Paper No. 15 filed on 5 April 2002, Claims 23-34 the newly amended claims were deemed partially unresponsive, and in the interests of compact prosecution, the claims were re-restricted to two groups. Group I of the of the Restriction Requirement or 5 April 2002 are drawn to methods not of originally presented claims. Group II of the Restriction Requirement of 5 April 2002 correspond to the Group III kit product of the originally presented claims.

In Paper No. 16 filed on 13 May 2002, applicant requested amendment of Claims 23, 24, and 29. The amendment of the claims of 13 May 2002 have been entered.

In Paper No. 16 filed on 13 May 2002, applicant elects with traverse, Group I of the Restriction Requirement of Paper No. 15, of Claims 23-28 and 33-34, drawn to a method of identifying a male sterile transgenic ***Brassica*** plant, seed, or parts thereof, by probing immobilized transgenic plant nucleic acids by chemical hybridization with a DNA fragment, or by PCR amplification of transgenic plant DNA templates.

In Paper No. 6, Applicants traverse the restriction requirement of Paper No. 15 on the grounds that: "All of the claims of the application relate to the single inventive concept of plants that comprise elite event MS-B2" (See page 3), and that "any search encompassing methods comprising the MS-B2 elite event will certainly encompass kits for said identification" (See page 4); that "independent claim 29 of Group II is clearly specific to the identification of 'elite event MS-B2 in biological samples", and "...the flanking regions represented in SEQ ID No. 8 and SEQ ID No. 10 are specific for the elite event" (See pages 3-4); and that examinations in applications of related but patentably distinct inventions have considered kits and methods during an examination, and that said examination is "direct evidence" that kits and methods as claimed are not considered to be distinct, independent inventions by the USPTO (See page 4).

Applicant's arguments have been considered, but are not deemed persuasive because:

The claims of the instant application, both originally presented and amended, are drawn to independent and distinct inventions, as discussed in Paper No. 15. As discussed in Paper No. 15, Groups I and II are related as product and process of use, and applicant's assertion that the Groups encompass "a single inventive concept" merely reflects that relationship, as discussed in Paper No. 15. Furthermore, applicant fails to rebut any of the reasons for the distinctness of the Groups as discussed in the Restriction Requirement of Paper No. 15, on page 2, line 24 to page 3, line 29.

An argument of specificity in regards to Claim 29 is inaccurate. Claim 29 as originally presented broadly reads on comprising any primer either side of a midpoint of a construct comprising and vector plasmid DNA fused to ***Brassica*** DNA; and in its current amended language reads on a kit comprising any primer either side of a midpoint of a construct comprising the same vector plasmid DNA fused to **rice** DNA, when the disclosed SEQ ID Nos. of the claims are unchanged by the amendment of the originally presented claims. The broad language of the claims have been read in the broadest and most reasonable interpretation, on their own merits, and in light of the instant specification.

In regards to applicant's assertion of patent prosecutions that they deem related, are "direct evidence", applicant is advised that patent prosecution is specific to the specification and claims of an instant application, and that comparisons to other applications and prosecution histories are not probative, because claims are restricted or examined on the particular merits and issues that are specific to the particular claim language and disclosure of an application.

The Restriction Requirement of 5 April 2002 is still deemed proper, and is therefore made FINAL.

Newly amended Claims 23-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 23-28 are drawn to methods of identifying a transgenic **rice** plant, or parts thereof comprising an "elite event MS-B2". An "event" is defined in the instant specification as a "(artificial) genetic locus that, as a result of genetic manipulation, carries a foreign DNA

comprising at least one copy of the gene(s) or interest", and that an "MS" event refers to and event carrying a transgene comprising "TA29-barnase" (See page 13, lines 15-19). An "elite event" is defined in the instant specification as "an event which is selected from a group of events, obtained by transformation with the same transforming DNA or by back-crossing with plants obtained by such transformation with the same transforming DNA or by back-crossing with plants obtained by such transformation, based on the expression and stability of the transgene and its compatibility with optimal agronomic characteristics of the plant comprising it" (See page 14, lines 3-7). The instant specification discloses that MS-B2 is an elite event specific to *Brassica* (See page 17, lines7-10; page 17, line 20). Applicant further defines MS-B2 in the disclosure, as being limited to a recombination of a pTCO113 plasmid in a genomic region of a nondisclosed chromatid or linkage group of the A-genome of the allotetraploid *Brassica napus* genome (See page 19, lines 18-23; and 34, lines 1-2).

The broadest and most reasonable interpretation of the claims in light of the specification is that an "elite event MS-B2" is descriptive proprietary and arbitrary term that is used with an intent to include a designation of a genus class of one, or possibly two, orthologous regions of a *Brassica* A-linkage group-derived genome, as exemplified by the A-genome of *Brassica napus*, as the claimed invention.

Furthermore, Applicant contradictorily asserts on page 3 of Paper No. 16 that the invention of the instant application is "clearly specific to the identification of an 'elite event MS-B2 in biological samples', and thus cannot be understood to relate to a kit for identifying other viruses or organisms". Clearly, rice is a different organism from *Brassica napus*.

Accordingly, Claims 23-32 are deemed as being drawn to a nonelected rice invention or nonelected Group, and are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim.

Claims 33-34 are examined in the Office Action that follows.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van*

Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, 14-16 of copending Application No.09/430,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Claims 33-34 of the instant application are broadly drawn to methods of analyzing seeds comprising elite event MS-B2, comprising PCR-fingerprinting diagnostic steps, or alternative RFLP fingerprinting steps.

Claims 1-5, 7-9, and 14-16 of the copending application broadly claim a transgenic plant, and parts thereof, including seeds, comprising an "elite event" MS-B2, that is characterized by methods steps comprising the same disclosed PCR-fingerprinting diagnostic steps, or alternative RFLP fingerprinting steps; and the method of characterizing said plants and parts thereof.

The claims of the copending application claim methods for plants, plant parts, and seeds, and the claims of the instant application claim methods for seeds.

The claims of the copending application claim the same starting plant material germplasm as that of claims 1-5 and 7-9 of the instant application.

The claims of the copending application comprise the same method steps of the detection of polymorphic molecular markers in a diagnostic fingerprinting assay, which comprise the making of an amplicon as a diagnostic polynucleotide fragment known by one of ordinary skill in the art as a Sequence Characterized Amplified Region (SCAR) molecular marker diagnostic; or alternatively, the claims of the copending application provide for a method comprising the utilization of said amplicon as a probe for the production of a Restriction Fragment Length Polymorphism (RFLP)-based fingerprinting diagnostic assay step.

It would have been obvious to one of ordinary skill in the art that the method claims of the instant application differ in scope, with the claims of the copending application the broader in scope, comprising the claimed subject matter of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as generally narrative, incomplete and indefinite, failing to conform with current U.S. practice. Claim 33 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are: (1) an assessment of "purity". Furthermore, Claim 33 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. The omitted structural cooperative relationships are: the seed or seed sampling relationship to its "purity". There is no clear relationship of what structurally constitutes "purity" of a single seed or population of seed, as broadly recited by the claim. Claims 34 is narrative and incomplete for omitting essential steps for a screening process,

such omission amounting to a gap between the steps. The omitted step is an evaluation step of a diagnostic detection step. See MPEP § 2172.01.

Claims 33-34 are rejected as vague and indefinite for the recitation of "with a specific primer or probe which recognizes". The phrase is vague and indefinite because it is not drawn to any particular diagnostic reaction step, and is not art accepted. A molecular marker produced with a primer or a probe may function as data in a diagnostic assay, and an evaluation of a diagnostic assay such as a fingerprinting assay may allow a researcher to recognize an assay fingerprint correlated to a particular genotype and phenotype, but primers or probes are incapable of "recognition".

Claims 33-34 are rejected as vague and unclear in the recitation of "the 5' flanking region" and the "3' flanking region". The metes and bounds of what range of sequence constitutes the recited "3' flanking region" of SEQ ID NO:8 or SEQ ID NO: 10 is not defined in the instant specification and the claims are vague and unclear as to what range of sequence recited as "flanking", is intended to encompass.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to methods of identifying elite event MS-B2 in *Brassica* seed of any species and cultivar, by utilizing detection of an MS-B2 specific region by a specific primer or probe. The recited primer and probes are narratively recited as having the vague property that they can "recognize" the "5' flanking region of SEQ ID No:8", or [alternatively] the "3'flanking region of SEQ ID No. 10". The recited "MS-B2" that is identified by the claimed method is interpreted as a genomic region of recombination and insertion of a pTCO113

plasmid into an A-genome of an exemplified *B. napus* genome, which produces a stable phenotype of male sterility, wherein said stable male sterility is interpreted to optimally require A-genome specific enhancer regulatory elements. (See for example the instant specification on page 2, lines 18-23; page 4, line 13 to page 6, line 6;page 9, lines 11-23; page 13, lines 15-19; page 14, lines 3-7; page 17, lines 7-20; page 19, lines 18-23; and page 34, lines 1-2).

Reynaerts et al (1993. Scientiae Horticulturae 55(1-2):125-139) teach that the availability of MS-B2 designated lines of all *Brassica* species, essential to the practice of the claimed invention, is unpredictable, because a large number of S-allele incompatibility systems prevent transmission by sexual crossing (See page 130, lines 4-16).

Rong et al (1996. Acta Botanica Sinica 38(7) :582-585) teach that the determination of a *Brassica napus* transgenic plant as male sterile (which is a characteristic of an MS-B2 designation) by an analysis of stable integration by RFLP and Southern blot analysis, in the absence of an evaluation of the plants over a range of temperatures, is unpredictable. Rong et al teach that a PTA29-*barnase* transgene was transformed into *Brassica napus*, and that successful transformation was analyzed by Southern blot assays with *BamHI* digested genomic DNA from plants and a *barnase* probe (See Figure 1 on page 584 and Figure 4 on page 585). Rong et al teach that when grown under controlled conditions, said PTA29-barnase comprising transgenic *Brassica napus* lines all appeared to be male sterile, but when said plants were grown under conditions in which the temperature exceeded 25 degrees Celsius, that 90% of their Brassica napus lines reverted to male fertile, and that either the activity of a barnase enzyme is temperature sensitive, or that unknown allelic factors associated with the transgenes resulted in the transgenes functioning as temperature sensitive alleles (See Abstract on page 582).

Goring et al (1991. Proc. Natl. Acad. Sci. 88:1770-1774) teach that the state of the art for a transgene insertion into a specific region of a genome, for the intent of conferring a particular phenotype, is such that "positional" effects unpredictably alter regulation of the intended expression pattern of any particular transgenes (See Goring et al on page 1770, column 1, lines 1-30).

Thomas et al (1994. Mol. Gen. Genet. 242-573) teach that the state of the art for a fingerprinting assay using molecular markers as diagnostic assays to assess and distinguish particular transgene insertions in different regions of the genome, are that said fingerprints assays

are primarily performed with an RFLP-diagnosis of autoradiograms of gel-fractionated and blot–immobilized fragments of genomic DNA that have been hybridized with a transgene-derived probe; or with a SCAR-diagnosis of gel-fractionated amplicons produced by Polymerase Chain Reaction (PCR) procedures. Thomas et al teach that the state of the art for said RFLP or SCAR diagnostic procedures requires the development of specific primers and probes; and the development of specific chemical hybridization conditions for successful use of said primers and probes in said diagnostic methods (See page 573, column 2, line 47 to page 576, column 2, line 15; Figures 1 and 2 on pages 577-578; page 577, column 2, line 44 to page 583, column 1, line 59).

Knapp et al (1994. Mol. Gen. Genet. 243:666-673) and Thomas et al (1994. Mol Gen. Genet. 242:573-585) teach that the determination of a particular insertion site of a T-DNA comprising transgene into any one plant cultivar or plant species, which are essential starting materials for the claimed invention, is unpredictable in the absence of genetic mapping of the insertion site (See Knapp et al on page 666, column 2, line 1 to column 1, line 46; page 667, column 2, line 34 to page 668, column 1, line 47; and page 670, column 1, line 21 to page 671, column 1, line 22; and see also Thomas et al on page 573, column 2, lines 47-50; and page 580, column 1, lines 5-20).

Furthermore, Knapp et al and Thomas et al teach that it is unpredictable whether sib-related T-DNA comprising transgenic plants, when probed with a DNA probe specific to a region of plant genomic DNA flanking the T-DNA transgene insertion site, will produce an orthologous RFLP or SCAR allelic molecular marker (See Knapp et al in Figure 3; page 669, column 2, line 3 to page 670, column 1, line 2), and also see Thomas et al in Figure 5 on page 580, page 579, column 2, line 6 to page 580, column 1, line 3; page 582, column 2, line 10 to page 583, column 1, line 38). Furthermore, Thomas et al teach a comparison of when probes for a RFLP diagnostic analysis are made by inverse PCR (iPCR) methods, and the gel fragment profile of iPCR fragments used as probes; with that of a SCAR diagnostic method (See for example Figure 5 on page 580; and page 574, line 13 to page 576, column 2, line 15). Thomas et al teach that said comparison of RFLP to SCAR molecular markers in the same sib-progeny, unpredictably failed to produce the same distribution pattern of polymorphisms across the same population of progeny (See Figure 5 on page 580).

Eshed et al (1996. Genetics 143:1807-1817) teach that determination of a phenotype based on a singular cosegregating set of molecular markers, is unpredictable for successful marker-aided identification of a genomic introgression produced by sexual hybridization. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (See Figures 1-2 on pages 1810-1812; and page 1815, column 1, line 1 to page 1816, column 1, line 1). Eshed et al further teach for example in Figure 4 on page 1814, that a singular set of cosegregating molecular markers cannot predict the effect or extent of a phenotype introgression, as exemplified by polymorphisms of molecular TG50B and TG-141, and a trait of brix expression.

Mariani et al (1990. Nature. 347(737-741) teach that the utilization of a TA29-derived polynucleotide probe, when utilized with Southern blot diagnostic assays, is unpredictable as a diagnostic assay for the recognition of male sterile tobacco and *Brassica napus* transgenic plants comprising an introgressed TA29-Barnase expression cassette, because said transformation is unpredictable in producing male-sterile plants (See page 738, column 1, lines 2 to line 60; and page 739, line 3 to page 740, column 2, line 2).

The instant specification fails to provide guidance for the use of probes that are narratively recited as having the vague property that they can "recognize" the "5' flanking region of SEQ ID No:8, or [alternatively] the "3'flanking region of SEQ ID No. 10". Applicant fails to provide guidance for any particular procedure for utilizing or making any specific probe, or any specific chemical or environmental conditions for its use in the recited method, that would be essential to make and use the claimed invention.

The instant specification fails to provide guidance for a determination of a defined male sterile "MS-B2" for plants grown at all growth conditions as broadly claimed, given the unpredictable effect of temperatures above 25 C, as discussed above. One of skill in the art would know that certain field sites would exceed 25 C when anther development occurs, with broadly claimed *Brassica* species, and certain *Brassica napus* varieties grown in hotter climes worldwide, and provided the unpredictability of PTA29-barnase-comprising plants, responsive to temperature conditions, as described above, applicant fails to disclose support for a broadly claimed trait of complete male sterility.

Applicant fails to provide guidance for all transgenic plants any *Brassica* species that comprise an A-genome. With the known unpredictability of epistatic effects, as discussed above, it is unclear what specific genomic polymorphisms would comprise any of the broadly claimed *Brassica* species, accessions and cultivars, and retain a male sterile phenotype consistent with the MS-B2 definition of the instant specification. The methods broadly claim all *Brassica* species and cultivars comprising a "MS-B2" event, but applicant only discloses a transfer of a singular *B. napus* MS-B2-designated transgene insertion into a single *B. juncea* A-genome-comprising cultivar by sexual hybridization, and further fails to disclose any molecular or genetic markers to support an A-genome to A-genome recombination in all plants as broadly claimed. What constitutes the metes and bounds of an "MS-B2" in the disclosed *B. juncea* is unclear, because the alternate definition of MS-B2 as comprising the same "elite event" transferred by sexual crossing to any other *Brassica* species, redefines an entirely different and broad structure of what constitutes MS-B2, that is vague when used in the context of defining an introgression of a PTA29-*barnase* gene in the exemplified *B. napus* plants; and applicant fails to disclose any genetic mapping data support for all broadly claimed *Brassica* plants. Applicant fails to disclose the metes and bounds of the *B. napus* and PTA29-*barnase*-comprising genomic introgression of any *B. napus* genome into *B. juncea* genome, and without a clear physical definition of what defines an MS-B2 event, in terms of any specific genomic characterization, or in relation to the male-sterility phenotype that is used to define what is MS-B2, it would be unclear to one of skill in the art how to make and use the broadly claimed invention. Accordingly, although specific methods disclosed in the instant specification may be utilized to distinguish MS-B2 *B. napus* plants from sib-plants that are not transgenic, but are male sterile; the broadly claimed methods are not enabled so that one of skill in the art can predictably make and use the invention as broadly claimed.

Given the claim breadth, the unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one of skill in the art to make, use, and evaluate all of the broadly claimed method embodiments for an analysis of all transgene-comprising and essential *Brassica* species starting materials, with the totality of all molecular markers and combinations of all RFLP-diagnostic and PCR-based diagnostic processes and method steps, as broadly claimed.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel essential plant starting materials. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available; the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each claimed embodiment is generally considered adequate. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that Applicants have deposited the two seed deposits ATCC Accession Numbers PTA-850 and PTA-2485, wherein each deposit comprises 50% MS-B2 seed, and %0% of seed of unknown composition and origin; and the conditions of the deposit remain unclear. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

The conditions of the deposits for meeting the criteria for a deposit as set forth in 37 C.F.R 1.809 and 35 U.S.C. 112 are unclear because a statement of the composition of the seed mixtures deposited as ATCC PTA-850 and PTA-2485 are not disclosed in the instant specification, for the examiner to determine whether the claimed MS-B2 seeds may be distinguished from the other unexemplified seeds in the deposited mixtures. For example, Reynaerts et al (1993. Scientiae Horticulturae 55(1-2):125-139) teach that an F1 progeny population made with a first parental of a PTA29-*barnase* transformed plant, crossed to a second PTA29-*barstar* transformed plant, may exhibit a trait of male sterility in 50% of its F1 progeny (See page 129, lines 7-19); and accordingly may share for example common vector and PTA-29 promoter sequences, in comparison to the MS-B2 region of the claims. Furthermore, the instant application currently fails to provide a deposit statement in accordance with sections (a)-(e) discussed above.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 33-34 are broadly drawn methods with essential polynucleotide sequences comprising any primer of any length and sequence , which primer or probe somehow "recognizes" 5' or 3' flanking regions of an undefined length and sequence; said methods performed with undefined hybridization steps requiring undefined reaction conditions. Claim 33 is further broadly drawn to a method of identification and discrimination of seed of any *Brassica* species or cultivar, that comprise a singular introgression of recombinant portion of an A-linkage group genome of *Brassica napus* and a PTA-29-barnase transgene cassette, as an elite event MS-B2, wherein MS-B2 is defined as an insertion event which confers a trait of male sterility in *Brassica napus*. The "confirming seed purity" of the claims is unclear, as discussed in

the 35 U.S.C. 112, second paragraph rejection above, but interpretation of the phrase includes the identification of transgenic elite event-defined MS-B2 seed from other seed.

The instant specification only provides guidance for particular nucleotide sequences of essential primers of specific chemical composition; for particular genomic DNA templates for chemical hybridization; for particular genomic DNA for analysis with the method, comprising a genomic plasmid introgression of a transgenic plant whose seed in part has been deposited as a 50% MS-B2-comprising mixture of seed as ATCC Accession No. PTA-850 or PTA-2485; and for pTCO113-derived plasmid polynucleotides, including those comprising an A-genome *B. napus* genomic sequence, cloned from an MS-B2 comprising PTA-850.

The instant specification fails to describe any other of the broadly claimed multitude of nondisclosed genomic DNA templates of a multitude of plants of all Brassica cultivars and species; any of the other multitude of primers and probes of nondisclosed length or chemical composition; or any other specific method steps using said broadly claimed primers and probes.

The instant specification only provides for *Brassica juncea* interspecific hybrids comprising a *B. napus* introgression recombined into the *B. juncea* genome by sexual crossing methods; and for identifying an elite event of MS-B2 by a cloning and sequencing method with a chimeric pTCO113-derived plasmid comprising genomic DNA of the A-genome from a transgenic *Brassica napus* plant.

The instant specification fails to describe any other *Brassica* A-genome characterizations; independent transformants of other A-genome-comprising *Brassica* species other than a *B. juncea* plant line; or any genomic characterization of said B. juncea-derived plant line.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California V. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the

species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

See also University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997) which teach that the disclosure of a process for obtaining DNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Since the extent of any MS-B2 *B. napus* introgression that would confer the phenotypic trait of male sterility in all *Brassica* species and cultivars is not disclosed in the instant specification, which is essential to the broadly claimed invention, the method invention is not adequately described for screening all populations of all *Brassica* species comprising all MS-B2 insertion populations. Furthermore, in the absence of an adequate description of the totality of all of the molecular markers and the totality of all of the essential starting plant materials, as broadly claimed , it is not clear that the Applicant was in possession of the genus of all of the methods comprising all of the nonspecified method steps, plant materials, and molecular markers with the characteristics as broadly claimed. Furthermore, because Applicant has not described a representative number of any MS-B2-containing plants with the phenotypic characteristics as defined in the instant specification, to be identified by the methods as recited in the claims, Applicant has not adequately described the claimed genus.

Hence, The specification does not provide an adequate written description of the broadly claimed genus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-34 are rejected under 35 U.S.C. 103(a) as obvious over Mariani et al (1990. Nature. 347:737-741).

The claims are broadly drawn to methods of identifying elite event MS-B2 in *Brassica* seed of any species and cultivar, by utilizing detection of an MS-B2 specific region by a specific **probe**. The recited probe of the claims are narratively recited as having the vague property that they can "recognize" the "5' flanking region of SEQ ID No:8", or [alternatively] the "3' flanking region of SEQ ID No. 10".

Mariani et al teach a method to recognize and distinguish a male sterile TA29-barnase transgene transformed *Brassica napus* plant, comprising the steps of : utilization of a TA29-derived polynucleotide probe, with Southern blot diagnostic Restriction Fragment Length Polymorphism (RFLP) assays, to determine diagnostic RFLPs; and an analysis of *B. napus* male and female fertility in said transgenic plants, comprising morphological examination of the anthers, and pollination of the transgenic pistils with pollen from nontransformed plants. (See page 739, line 3 to page 740, column 2, line 2).

Mariani et al teach that a sufficient number of restriction enzyme digests were utilized, and analyzed for each individual transgenic *Brassica napus* plant, which included restriction enzyme sites in plant genomic DNA regions flanking the PTA29-barnase which did not occur

more than once within the sequence of the transgene construction, to identify the copy number of transgene insertions of each of the transformed plants.

Mariani et al do not teach a diagnostic analysis specifically for seeds.

Mariani et al suggest that genomic polynucleotide templates for TA-29-derived probes can be utilized from various plant parts of a transgenic plant transformed with a TA29-barnase transgene (See Figs. 2-4 on pages 739-740; page 738, column 1, line 2 to page 740, column 2, line 2).

It would have been obvious for one of ordinary skill in the art to use PTA29-barnase transformed *Brassica napus* plants and PTA29-derived probes, and combine them in a method to use an RFLP diagnostic specific for a particular genomic introgression of transgene into a transgenic male-sterile plant, as taught by Mariani et al, and to use said methods and plant materials to alternatively screen seeds, as suggested by Mariani et al, to screen for transgenic plant genotypes with particular RFLPs correlated with male sterility. The choice of the restriction enzymes for the method taught by Mariani et al, including the inexpensive *EcoRI*, *Hind III*, and *EcoRV*, would be an obvious design choice for one of ordinary skill in the art. The PTA29-derived probe taught by Mariani et al would inherently hybridize to an MS-B2-comprising genomic template, as broadly claimed.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francis Moonan, whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:00 PM (E.S.T.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4315. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-196.

Francis Moonan, Ph. D.
30 July 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638